

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE CARACO PHARMACEUTICAL
LABORATORIES, LTD. SECURITIES
LITIGATION

) Case No. 2:09-cv-12830-AJT-DAS

) CLASS ACTION

) **ORAL ARGUMENT REQUESTED**

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS
THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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INTRODUCTION

This Court must dismiss the Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws (“Amended Complaint”) with prejudice. The factual allegations in the Amended Complaint are insufficient to create a pleading that is “plausible on its face” and, as a result, Plaintiffs have failed to “nudge” their claims across the line from conceivable to plausible.¹ Nor have Plaintiffs provided this Court with any authority supporting their position. The majority of cases cited by Plaintiffs are unpublished, outside the jurisdiction, or entirely distinguishable.

Plaintiffs’ most glaring error is their reliance upon a string of cases in which courts denied motions to dismiss because the defendants in those cases concealed from shareholders the fact that the companies had received Form 483s from the Food and Drug Administration (“FDA”).² That is not the case here.

I. The alleged misrepresentations were not material.

Defendant Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) fully disclosed to its investors all Form 483s, as well as the Warning Letter, that it received from the FDA. None of

¹ To survive a motion to dismiss, a complaint must contain sufficient factual allegations to state a claim for relief “that is plausible on its face.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The allegations in the complaint must produce an inference of liability strong enough to “nudge” the plaintiff’s claims “across the line from conceivable to plausible.” *Iqbal*, 129 S. Ct. at 1952; *Twombly*, 550 U.S. at 570.

² See, e.g., *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1119 (C.D. Cal. 2005); *McGuire v. Dendreon Corp.*, No. C07-800, 2008 WL 5130042, at *2 (W.D. Wash. Dec. 5, 2008); *In re Zenith Labs. Sec. Litig.*, No. 86-3241A, 1993 WL 260683, at *5 (D. N.J. Feb. 11, 1993); Cf. *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1021 (S.D. Cal. 2005) (company failed to disclose negative clinical study results to investors); *In re Indep. Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 760 (S.D.N.Y. 2001) (company failed to disclose that it was the target of an investigation by the United Kingdom’s energy regulator); *In re Able Labs. Sec. Litig.*, No. 05-2681, 2008 WL 1967509, at *2 (D.N.J. Mar. 24, 2008) (company did not receive FDA Form 483 until six weeks after the end of the class period).

the Defendants withheld information regarding the FDA's assessment of Caraco's regulatory compliance from the investing public.³ Am. Compl.⁴ ¶¶ 106, 112, 114, 122 & 131. During the putative class period, the Plaintiffs knew that Caraco's record with the FDA was not flawless. The facts regarding the FDA's investigations of Caraco were publicly available. Any investor could have viewed the Warning Letter or the Form 483s on the FDA's website. The second sentence of the Warning Letter clearly states that the FDA's inspection from May 1 to June 11, 2008 "revealed significant deviations from current Good Manufacturing Practice (cGMP) regulations" Defendants' Memo.,⁵ Ex. E.

Caraco could not have predicted that the FDA would initiate a seizure,⁶ but nevertheless warned investors of that possibility. Defendants' Memo. at 2, 12. Despite Caraco's explicit

³ Despite Caraco's transparency with the investing public, Plaintiffs essentially argue that Caraco should have done more—*i.e.*, Caraco should have disclosed every manufacturing problem that came to management's attention. But that is not the standard. "[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact." *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993); *In re United Am. Healthcare Corp. Sec. Litig.*, No. 2:05-cv-72112, 2007 WL 313491, at *14 (E.D. Mich. Jan. 30, 2007) (company had no duty to disclose its allegedly illegal marketing practices and possible negative consequences "even if investors would have very much liked to have known this information").

⁴ In this Reply Brief, "Am. Compl." refers to the Plaintiffs' Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws, filed with this Court on February 11, 2010.

⁵ In this Reply Brief, "Defendants' Memo." or "Defendants' Memorandum" refers to the Defendants' Memorandum of Law in Support of their Motion to Dismiss the Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws, filed with this Court on April 12, 2010.

⁶ Plaintiffs blame the seizure for the decline in Caraco's stock price at the end of the putative class period. Am. Compl. ¶¶ 135, 136. In the absence of the seizure, there is no basis for Plaintiffs' alleged damages. Plaintiffs' claims therefore hinge on Caraco's failure to advise investors that an FDA seizure was certain to occur. Yet, the Defendants had no duty to predict "future regulatory actions or losses the company may suffer as a result." *In re United Am. Healthcare Corp. Sec. Litig.*, 2007 WL 313491, at *8. Caraco simply cannot be held liable for failing to predict the future. *See In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 633 (E.D. Mich. 2001).

warnings to investors that noncompliance with FDA rules could result in fines and other judicially-imposed sanctions, including product seizures and injunction actions, Plaintiffs falsely accuse the Defendants of “downplaying,” “minimizing,” or not “fully disclosing” the risks. Opp. Br.⁷ at 13, 24.

The United States Court of Appeals for the Sixth Circuit has flatly rejected Plaintiffs’ notion. *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 402 (6th Cir. 1997). The Circuit teaches in *Sofamor Danek* that even though a company (Sofamor Danek) “downplayed” the significance of an FDA warning letter, there was no violation of federal securities laws because “any analyst could easily obtain a copy of the letter and could make an independent judgment of its significance.” *Id.* Even if the Defendants downplayed the FDA’s letters (which they did not), *Sofamor Danek* instructs that such is not actionable under federal securities laws.

In fact, this case is distinguishable from *Sofamor Danek* because Caraco did not downplay the situation. It even went so far as to direct investors to the FDA’s website. Am. Compl. ¶ 114.

Finally, although the Plaintiffs urge this Court to ignore Defendants’ argument at the motion-to-dismiss stage, the Sixth Circuit has not rejected the truth-on-the-market defense. *Ley v. Visteon Corp.*, 543 F.3d 801, 811 (6th Cir. 2008). Instead, the Sixth Circuit has “voiced the logical compliment” in *Helwig v. Vencor*, 251 F.3d 540 (6th Cir. 2001), where the court concluded that the statements at issue were material because the information was “‘known exclusively’ to the defendants.” *City of Monroe Employees Retirement Sys. v. Bridgestone Corp.*, 399 F.3d 651, 675-76 (6th Cir. 2005). In contrast, Caraco was candid with shareholders

⁷ In this Reply Brief, “Opp. Br.” refers to the Plaintiffs’ Opposition to Defendants’ Motion to Dismiss the Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws, filed with this Court on May 27, 2010.

about the FDA's warnings and disclosed all risks. Defendants' Memo. at 11-13. Together, the FDA and Caraco told investors about the full range of possible sanctions.⁸

Consequently, the Amended Complaint must be dismissed with prejudice, because the Defendants did not misrepresent any fact, or omit to state any material fact, to the investing public. This case is nothing more than allegations of fraud by hindsight,⁹ which must be rejected.

II. All of the allegations in Plaintiffs' Amended Complaint, examined collectively, do not give rise to a strong inference of scienter on the part of any Defendant.

When evaluating whether a complaint adequately alleges scienter, a court "must consider plausible nonculpable explanations for the defendant's conduct." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323-24 (2007). The Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, and the *Tellabs* decision "make clear that the burden of proof, at this stage of the proceedings, rests with the investors," not with the Defendants. *Konkol*, 590 F.3d at 403. Plaintiffs do not carry their burden.

A. Plaintiffs have not satisfied their burden of demonstrating that a nonfraudulent explanation for Defendants' conduct is less plausible.

Plaintiffs have failed to "establish an inference of scienter that is more plausible and powerful than competing inferences of defendants' state of mind." *Nicholson v. N-Viro Int'l Corp.*, No. 3:06CV01669, 2007 WL 2994452, at *4 (N.D. Ohio Oct. 12, 2007). According to Plaintiffs, the "mere existence" of a pervasive product variability issue "essentially means that the Company was neither cGMP compliant nor could any defendant 'believe' that Caraco was

⁸ Even prior to Caraco's disclosures, the investing public knew that the FDA could seize drug product if it found violations. *See* Defendants' Memo. at 11.

⁹ *See, e.g., Konkol v. Diebold, Inc.*, 590 F.3d 390, 403 (6th Cir. 2009) (dismissing "classic fraud by hindsight case where a plaintiff alleges that the fact that something turned out badly must mean defendant knew earlier that it would turn out badly") (quotation omitted).

‘substantially compliant.’” Opp. Br. at 6. This allegation, which is based solely on claims from anonymous former Caraco employees, all of whom “have axes to grind,”¹⁰ does not nudge Plaintiffs’ Amended Complaint over the motion-to-dismiss hurdle. *See PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 684 (6th Cir. 2004) (even when a court concludes that the allegations “no doubt merit drawing *some* inference of scienter, that is not enough”).

Plaintiffs erroneously rely on *In re Copley Pharm., Inc. Sec. Litig.*, No. 94-11897, 1995 WL 169215 (D. Mass. Mar. 16, 1995), for their notion that if a company publicly states that it believes that it is in material compliance with cGMP standards and it is later determined to be out of compliance, the company’s statements about its beliefs are actionable under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. Opp. Br. at 22. In *Copley*, the Massachusetts federal district court dismissed all but one of the complaint’s allegations (a bribery allegation that is not at issue in this case) and held:

It must be remembered throughout analysis of this case that the alleged awareness by the defendants of certain problems in the process of production of Albuterol and Brompheril is not the equivalent of knowledge or belief that the Company was not in “material compliance” with FDA or cGMP standards.

Copley, 1995 WL 169215, at *2, *6 n.7. Plaintiffs’ allegation that Defendants’ supposed awareness of various problems in Caraco’s manufacturing process is the equivalent of their knowledge or belief that Caraco was not “substantially compliant” with FDA regulations similarly fails to establish scienter. *Copley* does not support Plaintiffs’ assertions and, instead, supports dismissal of the Amended Complaint.

Since the Plaintiffs do not allege facts to support the view that Defendants knew Caraco was not in compliance with cGMP, Plaintiffs must instead offer factual allegations to show that Defendants did not believe Caraco was substantially compliant with cGMP at the time that the

¹⁰ *Higginbotham v. Baxter Int’l Inc.*, 495 F.3d 753, 756-57 (7th Cir. 2007).

statements were made. Plaintiffs, however, simply do not allege any facts in the Amended Complaint that demonstrate Defendants did not act in good faith.

For instance, there is no allegation that Defendant Daniel H. Movens (“Movens”) told any of the confidential witnesses that he did not believe Caraco was substantially compliant with cGMP. Nor do Plaintiffs allege the existence of an internal memorandum or report that states any Defendant believes Caraco is out of compliance with FDA regulations. Because the Plaintiffs have failed to offer any factual allegations to show that Defendants’ statements “were not made in good faith,” the Amended Complaint must be dismissed with prejudice. *Sinay v. Lamsen & Sessions Co.*, 948 F.2d 1037, 1040 (6th Cir. 1991).

Plaintiffs’ scienter analysis relies on *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005). But, in *Yanek*, the California federal district court rejected the plaintiffs’ argument that the company’s history of product recalls and adverse events provided circumstantial evidence of scienter because information about the recalls was available to the public. *Yanek*, 388 F. Supp. 2d at 1126. “[U]nder the fraud-on-the-market theory, the market already had the necessary information to assess any impact of prior product recalls on FDA approval.” *Id.* (quotation omitted). Plaintiffs likewise overlook the fact that the FDA had already informed the market about Caraco’s manufacturing problems. Once the FDA did so, the market had sufficient disclosure. *Sofamor Danek*, 123 F.3d at 402.

Finally, Plaintiffs falsely assert that Defendants “offer no more compelling inferences” than the Plaintiffs offer. Opp. Br. at 41. But the Sixth Circuit “has never held that a securities-fraud defendant must proffer a nonfraudulent explanation.” *Konkol*, 590 F.3d at 403. Regardless, the Defendants did in fact offer a more compelling, nonculpable explanation for their behavior. Defendants’ Memo. at 28-29. The Defendants truly believed that Caraco was in

substantial compliance with cGMP and worked to rectify any problems identified either internally or by the FDA. *Id.* “When a corporation, through its officers or otherwise, states an honestly held view based on the information currently before it, neither it nor its officers may be held liable, pursuant to Section 10(b) or Rule 10b-5.” *Sinay*, 948 F.2d at 1040.¹¹ The fact that the FDA may have come to a different conclusion than Caraco does not make the Defendants’ earlier statements fraudulent.

B. The facts alleged by Plaintiffs do not satisfy any of the *Helwig* factors.

Plaintiffs’ allegations fail to fall within the rubric of *Helwig*. Indeed, the absence of the *Helwig* factors in the Amended Complaint “indicates the absence of scienter,” mandating dismissal. *In re Diebold Sec. Litig.*, No. 5:05CV2873, 2008 WL 3927467, at *5 (N.D. Ohio Aug. 22, 2008).

1. *Defendants’ self motivation*

Plaintiffs claim that Defendants Movens and Dilip Shanghvi (“Shanghvi”) committed fraud because they were interested in “saving their salaries and bonuses.” Opp. Br. at 38. The Amended Complaint, however, contains no reference to their alleged financial benefits (*e.g.*, salary, bonus, stock options). A court must be able to find allegations supporting the *Helwig* factors in the complaint, not an opposition brief. *Konkol*, 590 F.3d at 403-04; *City of Monroe*, 399 F.3d at 684; *D.E. & J Ltd. P’ship v. Conaway*, 284 F. Supp. 2d 719, 744 (E.D. Mich. 2003). Besides the fact that the Court cannot consider Plaintiffs’ new “self motivation” allegations, Plaintiffs’ argument has no merit. “[A]n executive’s desire to protect his position within a

¹¹ See also *In re CBT Group PLC Sec. Litig.*, No. C-98-21014, 1999 WL 1249287, at *3 (N.D. Cal. July 21, 1999) (“[E]ven if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected. Management simply may have been confident that they could overcome the problems or merely underestimated the severity of such problems.”).

company or increase his compensation,” does not constitute a motive for fraud. *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 690 (6th Cir. 2004).

2. *Fraudulent statement followed by disclosure of inconsistent information*

Plaintiffs claim that the temporal proximity between Defendants’ false statements and the disclosure of the truth provide a strong inference of scienter. Opp. Br. at 35. Specifically, Plaintiffs allege that, although Caraco told investors that it initiated a voluntary recall of Digoxin in April 2009, FDA documents reveal that the recall was “FDA initiated.” Am. Compl. ¶ 128(a). Even if the FDA “talked the company into” conducting a recall, Am. Compl. ¶ 128(b), Caraco’s characterization of the recall as “voluntary” is nevertheless true. According to FDA documents, Caraco had discussions with the FDA about the potential health hazard, and Plaintiffs concede that, ultimately, Caraco “decided” to recall the product. Am. Compl. ¶ 128(b)(ii) (emphasis added). Caraco’s decision to recall its product is not the equivalent of an FDA-mandated recall. Plaintiffs have to allege more than mere semantic variances to cross the plausibility threshold and avoid dismissal. *See Twombly*, 550 U.S. at 570.

3. *Divergence between internal reports and external statements and disregard of most current factual information before making statements*

Plaintiffs vaguely assert that internal reports “alerted” Defendants “that there were severe problems with the quality of the pharmaceuticals produced by Caraco.” Opp. Br. at 31. This conclusory allegation fails to satisfy any of the *Helwig* factors. Plaintiffs do not offer any information from these alleged internal reports that confirms that Defendants knew their statements were false. *In re CBT Group PLC Sec. Litig.*, 1999 WL 1249287, at *2. Plaintiffs do not allege how they got the reports and who produced the reports. *Id.* Nor do Plaintiffs “provide any of these reports or cite any of their specific details.” *Grillo v. Tempur-Pedic Int’l, Inc.*, 553 F. Supp. 2d 809, 819 (E.D. Ky. 2008). In addition, other than one reference to a report received

by Movens followed by an allegedly contradictory public statement,¹² the Amended Complaint lacks any allegations regarding whether the other Defendants had access to any negative internal reports. Other courts have rejected similar efforts to cite internal reports without providing “adequate corroborating details.” *See, e.g., In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999). Thus, Plaintiffs’ general allegations of the Defendants’ receipt of negative reports are insufficient to support a strong inference of fraudulent intent.

CONCLUSION

Defendants’ Motion to Dismiss, with prejudice, should be granted for all of the reasons set forth in this Reply Brief and Defendants’ Memorandum. Plaintiffs have already had an opportunity to correct any pleading deficiencies when they filed the Consolidated Amended Complaint. The “purpose of the PSLRA would be frustrated if district courts were required to allow repeated amendments to complaints filed under the PSLRA.” *Miller v. Champion Enters., Inc.*, 346 F.3d 660, 692 (6th Cir. 2003). Because the PSLRA restricts Plaintiffs’ ability to amend, the Defendants respectfully request that the Court grant their motion and dismiss the Consolidated Amended Complaint with prejudice.

¹² Plaintiffs challenge the following comment by Movens in a press release: “We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business.” Am. Compl. ¶ 100. Plaintiffs contend that Movens’ remarks were fraudulent because he earlier received a report that four employees in the Dispensing Department did not have the minimum training requirements necessary for their jobs. Am. Compl. ¶ 101(a). Such a tenuous argument clearly does not create a strong inference of scienter. First, Plaintiffs make no allegations that specifically discredit Caraco’s recruiting efforts at local universities and technical schools. Second, Plaintiffs have alleged no facts that cast doubt on Movens’ genuine belief that Caraco was in substantial compliance with cGMP, even if four employees, out of a company total of 650 employees, lacked the necessary training. Am. Compl. ¶ 138. Finally, Movens’ general optimistic comments about Caraco’s training and recruiting are not actionable. *See In re Federal-Mogul Corp. Sec. Litig.*, 166 F. Supp. 2d 559, 562 (E.D. Mich. 2001) (“The Sixth Circuit has upheld the finding that ‘vague, optimistic statements’ are not material.”).

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I hereby certify that, on this 24th day of June 2010, I electronically filed the foregoing Defendants' Reply Brief In Support of Motion to Dismiss the Consolidated Amended Class Action Complaint with the Clerk of Court using the ECF system, which will send notification of such filing to the following counsel of record:

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